

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
201023

CHEMISTRY REVIEW(S)

**FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT**

Application: NDA 201023/000

Action Goal:

Stamp Date: 31-MAR-2010

District Goal: 24-MAY-2010

History: 30-SEP-2010

Applicant: SANOFI AVENTIS SPA
55 CORORATE DR
BRIDGEWATER, NJ 08807

Brand Name: CABAZITAXEL (XRP6258)

Estab. Name:

Generic Name:

Priority: 1

Product Number; Dosage Form; Ingredient; Strengths

Org. Code: 150

001; SOLUTION, CONCENTRATE; CABAZITAXEL; 60MG/1.5ML

Application Comment: PRIORITY PROSTATE CANCER NDA WITH SHORTENED REVIEW CLOCK- 8 WEEK REVIEW CLOCK. REQUEST COMPLIANCE OVERALL RECOMMENDATION BY 5/24/10 (on 08-APR-2010 by D. MESMER (HFD-800) 301-796-4023)

FDA Contacts:	D. MESMER	Project Manager	(HFD-800)	301-796-4023
	X. CHEN	Review Chemist		301-796-1337
	H. SARKER	Team Leader	(HFD-150)	301-796-1747

Overall Recommendation:	ACCEPTABLE	on 03-MAY-2010	by M. STOCK	(HFD-320)	301-796-4753
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**FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT**

Establishment: CFN: FEI: (b) (4)
(b) (4)
DMF No: AADA:
Responsibilities: (b) (4)
Estab. Comment: (b) (4)
Profile: OAI Status: NONE

<u>Milestone Name</u>	<u>Milestone Date</u>	<u>Request Type</u>	<u>Planned Completion</u>	<u>Decision</u>	<u>Creator</u>
<u>Comment</u>				<u>Reason</u>	
SUBMITTED TO OC	08-APR-2010				MESMERD
OC RECOMMENDATION	21-APR-2010			ACCEPTABLE BASED ON FILE REVIEW	STOCKM

FDA CDER EES ESTABLISHMENT EVALUATION REQUEST DETAIL REPORT

Establishment: CFN: 9610119 FEI: 3002808000

AVENTIS PHARMA LTD.

9 QUAL JULES GUESDE
VITRY-SUR-SEINE, , FRANCE

DMF No: (b) (4) **AADA:**

Responsibilities: DRUG SUBSTANCE LABELER
DRUG SUBSTANCE MANUFACTURER
DRUG SUBSTANCE PACKAGER
DRUG SUBSTANCE RELEASE TESTER
DRUG SUBSTANCE STERILITY TESTER

Estab. Comment: EMAIL FROM ELIZABETH PHILPY ON 4/7/10 INSTRUCTS THAT INFORMATION SUBMITTED FOR BOTH SANOFI-AVENTIS RECHERCHE & DÉVELOPPEMENT AT 13 QUAI JULES GUESDE AND SANOFI CHIMIE AT 9 QUAI JULES GUESDE SHOULD BE SUBMITTED UNDER THIS FEI NUMBER, 3002808000. SPONSOR INDICATES AT #13 QUAI JULES GUESDE: MANUFACTURING OF THE DRUG SUBSTANCE FROM (b) (4) AND (b) (4) AND MICROBIAL CONTAMINATION TESTING OF THE DRUG SUBSTANCE AT 9 QUAI JULES GUESDE: TESTING AND RELEASE OF (b) (4) TESTING AND RELEASE, PACKAGING AND LABELING OF THE DRUG SUBSTANCE. CONTACT NAME FOR #13 IS :MARIE-PIERRE IMBERT QUALITY ASSURANCE MANAGER MARIE-PIERRE.IMBERT@SANOFI-AVENTIS.COM TEL: 33.1.58.93.88.66 FAX: 33.1.58.93.30.61 (on 07-APR-2010 by D. MESMER (HFD-800) 301-796-4023) PLEASE REFER TO FACTS ASSIGNMENT IDS 1157497 AND 1157501, WHICH WERE ISSUED FOR THIS PRODUCT PRIOR TO SUBMISSION DUE TO THE EXPEDITED STATUS OF THE APPLICATION. (on 09-APR-2010 by M. STOCK (HFD-320) 301-796-4753)

Profile: NON-STERILE BULK BY CHEMICAL SYNTHESIS **OAI Status:** NONE

<u>Milestone Name</u>	<u>Milestone Date</u>	<u>Request Type</u>	<u>Planned Completion</u>	<u>Decision</u>	<u>Creator</u>
<u>Comment</u>				<u>Reason</u>	
SUBMITTED TO OC	08-APR-2010				MESMERD
SUBMITTED TO DO	09-APR-2010	Product Specific			STOCKM
ASSIGNED INSPECTION TO IB	16-APR-2010	Product Specific			JOHNSONE
DO RECOMMENDATION EXPEDITED COMPLIANCE REVIEW DONE BY DOUG CAMPBELL.	03-MAY-2010			ACCEPTABLE INSPECTION	STOCKM
OC RECOMMENDATION	03-MAY-2010			ACCEPTABLE DISTRICT RECOMMENDATION	STOCKM

**FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT**

Establishment: CFN: 9610433 FEI: 1000541557
AVENTIS PHARMA LTD.
RAINHAM ROAD SOUTH
DAGENHAM, , UNITED KINGDOM

DMF No: **AADA:**

Responsibilities: FINISHED DOSAGE MANUFACTURER

Estab. Comment: MANUFACTURING, TESTING AND RELEASE, PACKAGING AND LABELING OF THE DRUG PRODUCTS (CABAZITAXEL CONCENTRATE FOR SOLUTION FOR INFUSION AND SOLVENT FOR DILUTION) (on 07-APR-2010 by D. MESMER (HFD-800) 301-796-4023)

Profile: STERILE-FILLED SMALL VOLUME PARENTERAL DRUGS **OAI Status:** NONE

<u>Milestone Name</u>	<u>Milestone Date</u>	<u>Request Type</u>	<u>Planned Completion</u>	<u>Decision</u>	<u>Creator</u>
<u>Comment</u>				<u>Reason</u>	
SUBMITTED TO OC	08-APR-2010				MESMERD
SUBMITTED TO DO	08-APR-2010	10-Day Letter			STOCKM
DO RECOMMENDATION	16-APR-2010			ACCEPTABLE BASED ON FILE REVIEW	JOHNSONE
OC RECOMMENDATION	18-APR-2010			ACCEPTABLE BASED ON PROFILE DISTRICT RECOMMENDATION	INYARDA

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